Medical Ghostwriting

Ethical and Practical Controversies

What is medical ghostwriting?

- **AMWA**
  - "'Ghost authoring' refers to making substantial contributions without being identified as an author. 'Guest authoring' refers to being named as an author without having made substantial contributions. 'Ghostwriting' refers to assisting in presenting the author's work without being acknowledged. The term 'ghostwriting' is often used to encompass all three of these practices.[1]
- **Stretten, for *British Medical Journal***
  - "Ghostwriting occurs when paid or unpaid writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments. This practice is considered to be distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline."[2]

1. AMA Ethics FAQs. https://web.archive.org/web/20130716034114/http://www.amwa.org/amwa_ethics_faqs. Published September 2009. Accessed April 5, 2020. **2**. Stretten S. *BMJ Open*. 2014;4:e004777.

Prevalence

It is difficult to gauge the prevalence of ghostwriting because of secrecy and limited research conducted on the topic. Here are a few examples of surveys that have been performed:

- Flannigan *et al* surveyed authors from a randomly chosen list of 1, 179 articles. Questionnaires were returned by 809 corresponding authors. Of these, 11% indicated ghost authorship had occurred, and 85% of these had not been acknowledged (*JAMA*. 1998; 280:222-224).
- Mowatt *et al* surveyed prevalence of honorary and ghost authorship in Cochrane reviews. Of the 362 reviews, 39% had evidence of honorary authors, and 9% had evidence of ghost authors (JAMA. 2002; 287 (21): 2769-2771).
- Hamilton et al reported a web-based self-administered survey of AMWA and EMWA members found evidence of ghostwriting among medical writers. Specifically, in 2014, the mean weighted percentage of manuscripts with undisclosed contributions was 34%. (*Medical Writing*. 2016; 25 (1)).
- Tora L *et al* conducted a systemic search by looking through PubMed using different search terms like "ghostwriters and ghostwriting" and found evidence of ghostwriting ranging from <1% to 91% in varied settings using different methods and definitions of ghostwriting. (*Curr Med Res Opin*. 2019; 35 (9), 1643-1651).

Manuscripts are just the start

- Manuscripts for journals
- Presentations and posters for medical meetings
- Slides for symposia
- Cases/articles in self-study CME
- Health economic models based on clinical research
- Statistical analysis/chart creation

IMCJE: Who is an author?

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work AND
- Drafting the work or revising it critically for important intellectual content AND
- Final approval of the version to be published AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved[1]

IMCJE facilitates not including pharma-paid medical writers in list of authors:

*"All those designated as authors should meet **all four criteria** for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged."*[1]

1. International Committee of Medical Journal Editors. http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two. Accessed April 5, 2020.

Dangers of ghostwriting

Case studies: Vioxx and Prempro[1-6]

- In 2008, **Merck** faced legal action over claims that nearly 30,000 people experienced adverse cardiovascular events while taking the osteoarthritis drug, rofecoxib (Vioxx). Merck was accused of obscuring this risk by manipulating dozens of publications to promote rofecoxib.
- In 16 of the 20 clinical trial reports, Merck employees were reported authors on manuscript drafts, but the published study reported an academic investigator as the first author. In addition, the academic investigators were offered fees, but did not often declare financial support from the company.
- **Wyeth** was accused of writing favorable reports on its hormone replacement therapy (Prempro and Premarin). These papers emphasized unproven benefits and downplayed the risks of HRT, like breast cancer.
- In July 2009, a US federal court decision resulted in the release of at least 1500 documents which provided evidence of a substantial organized campaign by Wyeth of publication planning, including the use of ghost authors.

1. Ross JS, et al. *JAMA*. 2008 299:1800-1812; 2. Bosch X. *EMBO reports*. 2011;12(6):489-494;3. Krumholz H, et al. *BMJ*. 2007;334(7585):120-123; 4. http://news.legalexaminer.com/sen-grassley-questions-wyeth-ghostwriting-practices.aspx?googleid=253274;5. Barbour V. *Hematologica*. 2010;95(1):1-2;6. Fugh-Berman A. *PLoS Med*. 2010;7(9):e:1000335.

Taking responsibility

Recommendations that have been suggested to alleviate ghostwriting[1,2]

- Organizations, editorial associations, funding agencies, journals and publications should make an explicit commitment to avoid ghostwriting practices by specifically mentioning "ghostwriting" on their websites and specifying ghostwriting policies
- Adherence to International Committee of Medical Journal Editors (ICMJE) authorship criteria
- Follow professional guidelines like Good Publication Practices (GPP_3)
- Recommending stricter authorship guidelines to ascertain contributions of each author and obtain full disclosure of funding sources and financial ties
- Auditable authorship practices that align with these specific guidelines
- Barring faculty members from being listed as authors unless they make a substantive contribution
- Checklist of questions with scenarios spelled out to be as specific as possible

Tora L, et al. *Curr Med Res Opin*. 2019;3(9):1643-1651. Ghostwriting in Biomedicine: Bosch X. *EMBO reports*. 2011;12(6): 489-494.

Taking responsibility (cont'd)

Examples of what some journals are doing to mitigate ghostwriting? (Bosch, 2011)

- *The Oncologist* does not accept opinion pieces by writers linked to companies commercially interested in the content (Singer N, et al. *New York Times*, 2009).
- *Blood* recommends defining the interaction between professional writers and listed authors using the GATE criteria: **G**uarantee—are the authors guarantors of the work; **A**dvice—did the authors advise the writer?; **T**ransparency—is the writer acknowledged?; and **E**xpertise—did the author have sufficient expertise to draft the article? (Dunbar CF, et al. Ghostbusting at blood. *Blood*. 2009; 113:502-503; Daskalopoulou SS et al. *Curr Med Res Opin*. 2005; 21:307-310).
- The *International Journal of Clinical Practice* explicitly states that ghost and ghost authorship and failure to acknowledge significant contributions are unacceptable and liable to investigation (Bosch X. *EMBO reports*. 2011; 12(6)).
- *JAMA* requires that authors have had full control of their primary data, have carried out the statistical tests themselves, and have created tables and figures themselves (Gotzsche P et al. *PLoS Med*. 2009; 1000023).

Are we reducing ghostwriting

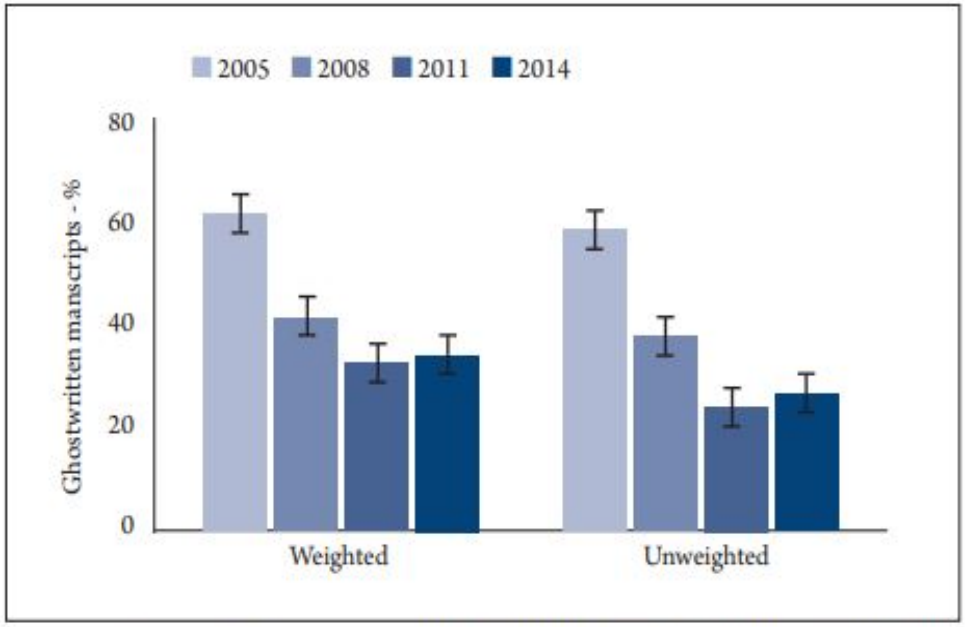

Figure 1. Prevalence of ghostwriting across survey years. Error bars represent 95% CIs.

Results of web-based surveys of AMWA and EMWA members were conducted in 2005, 2008, 2011 and 2014 and showed a 44% decrease in the rate of manuscripts with undisclosed contributions between 2005 and 2014, which is encouraging. In addition, univariate analysis showed that participants familiar with more authorship guidelines were less likely to have undisclosed contributions. (**Caveat:** survey participation was limited to AMWA and EMWA members who made substantial contributions to manuscripts). (Hamilton C, et al. *Medical Writing*. 2016; 25(1)).

- Hamilton et al (2016): Reduced from 2005-2011; some uptick from 2011-2014 (chart)
- Flanagin et al (2011): decline from 11.5% to 7.9% ghost authorship from 1996 to 2008, but still 21% showed evidence of honorary + ghostwriting (Flanagin A, et al. BMJ. 2011; 343: d6128.)

Ethical considerations

- Ghostwriting is inherently unethical
  - Deceives intentionally to gain advantage[1]
  - Turns scientific publications into covert marketing, damaging the credibility of science[1,2]
  - Creates "key opinion leaders" with less expertise than their many publications would indicate (because they didn't actually write the publications)[2]
- Ghostwriting masks poor evidence
  - Downplays or "spins" negative findings[3,4]
  - Lends gravitas to a so-so drug via multiple review publications[5]—"doesn't matter what they say as long as they spell the name right"
- Ghostwriting endangers public health and safety
  - Conceals or misrepresents drug safety and efficacy data[2]

1. Langdon-Neuner E. *Mens Sana Monogr*. 2008;6(1):257-273. **2.** Chen C-L. J Law Biosci.2018;5(1):84-102. **3**. Bosch X. *Eur Molec Biol Org Rep*. 2011;12(6):489-494. **4.** Barbour V. *Haematologica*. 2010;95(1):1-2. 5. Sismomdo S, et al. *J Pharm Pharmaceut Sci.* 2009;12(3):273-279.

Practical considerations

- Pharma has to get its drug research published/presented fast, to coincide with product launches
  - Needed to drive prescribing/contracts with managed care
  - Physician-researchers often too busy to get the articles written by deadlines
- Writers may become unemployable by refusing recognize degrees of culpability. Difference between:
  - Writing an entire journal article rubber-stamped by an expert versus cleaning up Power Point data sets already created by the expert for presentation at a meeting
- There are bigger problems in medical research—and sometimes ghostwriters can help to mitigate these problems:
  - Some statisticians believe that, apart from any ghostwriting, medical research is almost always wrong because of[1]:
    - Poor statistical power of studies (inadequate sample sizes/ small effect sizes)
    - Too much flexibility in study designs, definitions, endpoints, and analytical models
    - Investigator bias/pursuit of financial gain and recognition

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1.Ioannidis JA. *PLoS Med*. 2005;2(8):e124.

Discussion

What do you think?

- Is medical ghostwriting always wrong?
- Do we need to judge case by case, or should writers shun all forms of ghostwriting?
- Did you ever ghostwrite? What was it like and why did you take on the project?
- Should there be:
  - More publisher oversight?
  - Federal regulations prohibiting ghostwriting?—ghostwriting already can be included in product liability/misbranding lawsuits, but should there be actual rules like FDA rules regarding drug advertising?

…or whatever else you want to discuss!